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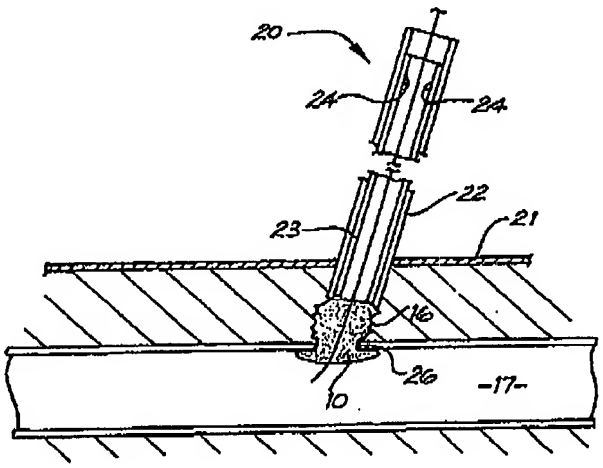
(54) Title: DEVICE FOR THE OCCLUSION OF A PUNCTURE IN A BODILY DUCT



(57) Abstract

A device for the occlusion of a puncture (26) in the wall of a bodily duct, such as an artery (17). The device comprises a resiliently compressible plug (10) that can be introduced into the puncture (26) from externally of the body, and introduction means (20) adapted to introduce the plug (10) into the puncture in a radially compressed state and to then release the plug within the puncture (26) so that it may expand to occlude the puncture. Also described is a method for occluding a puncture (26) in the wall of a bodily duct, such as an artery. The method includes the steps of (a) introducing a resiliently compressible plug from externally of the body into the puncture in a compressed state; and (b) releasing the compression from the plug so that it may expand in the puncture and occlude it.

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"Device for the occlusion of a puncture in a bodily duct"

Field of the Invention

The present invention relates to a method and means for the occlusion of a puncture in the wall of a bodily duct, such as an artery. More particularly, the invention relates to a method and means for the occlusion of punctures formed in the walls of arteries during intraluminal operative procedures.

Background Art

It is recognised that there can be a problem in staunching the blood flow from punctures formed in the wall of arteries during intraluminal operative procedures. During such procedures a needle is normally introduced into the artery and a catheter is then introduced into the artery. The operative procedures done intraluminally have become more complex. It has, in more recent times, become more common to use larger catheters than previously and to leave them in the patient for longer. Intraluminal procedures are now being used on older and more critical patients than were previously operated upon as they are so much less stressful for the patient than traditional open operative procedures. For these reasons there is an increasingly greater need for a method and means to staunch the blood flow from arterial punctures, and to occlude similar punctures in the walls of other bodily vessels.

This problem is typically dealt with by applying manual pressure to the wound site until the natural blood clotting mechanisms have had time to operate and seal the puncture. This can be time consuming and interrupt the flow of the operative procedure. Alternatively, a cut-down can be performed and the puncture sutured. However, this also is time consuming and requires a high level of surgical skill to perform.

It is known to position an anchor on the inside, ie. within the lumen, of a puncture in an artery and to position a sponge on the outside of the puncture and draw the two together with a suture for the purpose of occluding a puncture in an artery. Such devices are complex, expensive to produce and are considerably larger than is necessary to occlude a typical arterial puncture.

The present invention is designed to provide an alternative to the known methods and devices for the occlusion of punctures in the walls of bodily ducts.

Summary of the Invention

Throughout this specification, unless the context requires otherwise, the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to one aspect of the present invention, there is provided a device for the occlusion of a puncture in the wall of a bodily duct, the device comprising a resiliently compressible plug that can be introduced into the puncture from externally of the body, and introduction means adapted to introduce the plug into the puncture in a radially compressed state and to then release the plug within the puncture so that it may expand to occlude the puncture.

According to another aspect of the invention, there is provided a method for occluding a puncture in the wall of a bodily duct, the method including the steps of:-

(a) introducing a resiliently compressible plug from externally of the body into the puncture in a compressed state; and

(b) releasing the compression from the plug so that it may expand in the puncture and occlude it.

In preferred embodiments, the plug is formed with a region of reduced cross sectional area intermediate its ends. This region of reduced cross-sectional area is preferably bounded on at least one side, at the proximal end of the plug, by an enlargement such that once the plug has been deployed in the puncture and allowed to expand, it will resist withdrawal in a direction away from the, or each, enlargement. The cross-sectional shape and size of the intermediate region of the plug should be such that the intermediate region is able to occlude the puncture. Unlike the arrangements of known devices which are designed to bring about instantaneous haemostasis, in the present invention, it is the presence of the plug in the puncture that brings about its occlusion. The prior art devices require pressure on either side of the wall around the puncture to bring about occlusion. In the present invention, the enlargements of the plug on one or each side of the intermediate region of the plug, when present, serve to assist in preventing the plug from being displaced from the puncture.

In preferred embodiments of the invention. the enlargement at the proximal end of the plug is convex on its side facing into the bodily duct with a relatively long radius of curvature. The plug then presents a smooth profile to blood flowing past it. The distal end of the plug. which projects outwardly from the wall of the bodily duct, is preferably formed with ridges, or other projections that will inhibit movement of the plug towards the lumen of the vessel. If desired. different parts of the plug could be formed of material having different degrees of resilience. The plug could. for instance, have the enlargement or enlargements formed of a less dense, more resilient sponge than the intermediate region of the plug.

The face of the enlargement facing into the lumen of the bodily duct is preferably provided with an anti-coagulant coating. This could merely be an hydrophobic coating or it could be of a material having positively anti-coagulant properties.

The plug is preferably formed from a resorbable polymer or polycarbonate foam or sponge material. In a particularly preferred embodiment of the invention, the plug is formed of a polymer sponge that has an expansion ratio of from about 1.5:1 up to about 10:1. The plug may also be made, or partly constructed, of collagen sponge. It may be made partly of a resorbable material and partly of a non-resorbable material. It may however be made entirely of a non-resorbable material provided that it is bio-compatible and will not set up an inflammatory, or other. reaction in the patient. In a particularly preferred embodiment. the plug is made from polyurethane. In another preferred embodiment, the different parts of the plug may be made from different types of material. for instance, the proximal end of the plug may be made from a resorbable material while the remainder of the plug may be made from a non-resorbable material. The material of the plug may be naturally resilient such that it will spring back into shape as soon as a compressive pressure has been removed. Alternatively the plug may be formed of a material that is compressed or contracted through dehydration. In this case the resilience comes from the rehydration of the material forming the plug causing it to swell and occlude a puncture into which it has been placed.

In a preferred embodiment, the plug may contain within its structure, metallic wires or wireforms. These wires may be withdrawable after the plug has been deployed. or may. in the case of a non-resorbable plug. be a

permanent part of the plug. In one embodiment of the invention, these wires may be formed of Nitinol or another material that will change shape at the temperature of blood. In this way the wires could be designed to unfold like the ribs of an umbrella upon the proximal end of the plug being projected from the end of the plug delivery sheath into the blood stream in the duct. In a further preferred embodiment, the wires could be designed to unfold upon both the proximal and the distal end of the plug.

In a preferred embodiment, the proximal end of the plug is made from a thin layer of vascular graft prosthetic material such as polytetrafluoroethylene (PTFE), polyester or polyurethane with a wire or wireform (preferably made from shape-memory or self expanding material) internal the thin layer of vascular graft prosthetic material, such that when the plug is in place, the wire or wireform expands; thereby causing occlusion of the puncture.

The device, according to the present invention, is preferably deliverable to a puncture site through the introduction sheath that has already been inserted into the patient for the operation for which the puncture was formed in the first place. This has a distinct advantage over previous proposals for haemostasis devices where the original introduction sheath has had to be removed and a new sheath inserted into the puncture. Similarly, the original guide wire can be reused to guide the device according to the present invention into place in the puncture.

The device is preferably loaded into a plug delivery sheath that will slide into the existing delivery sheath but which is slightly longer than that sheath. Once the plug delivery sheath is in place, the original sheath can be withdrawn. The plug is then preferably pushed down the plug delivery sheath until the enlargement at the proximal end of the plug projects from the end of the sheath. If the plug delivery sheath is then withdrawn gently from the wound, the enlargement will engage against the inside of the vessel wall and be pulled free of the proximal end of the plug delivery sheath. If desired, a pusher may be provided inside the plug delivery sheath to assist in the ejection of the plug from the end of the plug delivery sheath. In particularly preferred embodiments of the invention, stop means are provided on the plug delivery sheath or on the pusher such that initially they may be moved relative to one another by an amount just sufficient to project

the enlargement of the plug beyond the end of the sheath. This feature prevents the plug from being fully deployed within the duct.

In practice, the plug delivery sheath is introduced into the patient at an angle. Thus, in a preferred embodiment, the plug is designed to have, in its compressed state, a configuration that follows the angled plug delivery sheath. This ensures that the plug will be in the correct position, ie. in line with the puncture upon deployment of the plug from the delivery sheath.

In another embodiment of the invention, the plug includes a main body having a proximal end and a distal end of greater cross sectional area than the proximal end wherein upon expansion of the plug, the proximal end is positioned within the lumen of the vessel and the distal end within the tissue surrounding the vessel.

In a preferred embodiment, the plug is funnel-like in shape. The plug is positioned within the puncture by means of a guidewire and a plug delivery sheath such that the free end of the guidewire extends into the lumen of the vessel. The guidewire has, disposed on its free end, a capture member which, upon withdrawal of the guidewire, abuts against the proximal end of the plug such that the proximal end of the plug is pulled internal the funnel-like structure of the plug thereby minimising the length of plug within the artery and therefore minimising obstruction of blood flow in the vessel.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Fig. 1 shows a partly cut away perspective view of a plug for inclusion in a puncture occlusion device according to the present invention;

Figs. 2 to 7 show diagrammatically the stages in the placement of the plug of Fig. 1 in a puncture in a bodily duct using a device according to the present invention, each figure showing a longitudinal sectional view through the duct and the device;

Figs. 8 to 12 show different embodiments of the invention as depicted in Fig. 1;

Figs. 13a and 13b show a different embodiment of the invention as depicted in Fig. 1; and

Fig. 14 shows an embodiment of the invention.

Preferred Mode of Carrying out the Invention

The device according to the present invention includes a plug 10 as shown in Fig. 1. The plug 10 is formed of a polymer foam, polycarbonate foam or sponge material that has an expansion ratio of from about 1.5:1 to about 10:1. At one end, the plug 10 is formed with a circular flange 11 which is convex on its lower surface 12 (as seen in Fig.1) and substantially planar on its upper surface 13. An intermediate portion 14 is connected to the middle of the face 13. This intermediate portion 14 is circular in cross section and is of a diameter which is smaller than that of the flange 11 but sufficient that in its expanded condition it will occlude a puncture into which it is positioned in use. The upper end of the plug 10 comprises a substantially cylindrical body 15 which is of a greater diameter than the intermediate portion 14 but smaller than the flange 11. Three radially directed, spaced apart, circumferential ribs 16 are provided on the cylindrical surface of the cylindrical body 15. The convex lower surface 12 is coated with an anti-coagulant material.

To position the plug 10 in a puncture 26 made in an artery 17 in connection with an intraluminal procedure the steps illustrated in Figs. 2 to 7 are followed. The puncture will normally have been made by the Seldinger needle technique in which a needle (not shown) is used to puncture the skin 21. The puncture could alternatively be formed in the artery 17 by a conventional cut-down technique. As is seen in Fig. 2, following the intraluminal procedure there will be in place in the artery 17 an introducer sheath 18 and a guidewire 19.

A device 20, according to the present invention, comprising the plug 10 disposed, in a compressed condition, in the proximal end of a plug introducer sheath 22 and a pusher tube 23 disposed in the plug introducer sheath 22 is slid down the introducer sheath 18 over the guidewire 19. The plug introducer sheath 22 is longer than the introducer sheath 18 so that the proximal end of plug introducer sheath 22 projects into the artery beyond the end of the introducer sheath 18 (see Fig. 3). With the plug introducer sheath 22 so positioned, the introducer sheath 18 can be withdrawn leaving the device 20 in place on the guidewire 19.

The pusher tube 23 is formed with a pair of detents 24 projecting from each side adjacent its distal end. The pusher tube 23 is pushed inwardly relative to the plug introducer sheath 22 until the detents 24 abut against the

distal end of the plug introducer sheath 22. This action will push the plug 10 out of the proximal end of the plug introducer sheath 22 until the flange 11 is free of the compressive force of the plug introducer sheath 22. The flange 11 will resiliently expand and project radially from the plug introducer sheath 22 (see Fig. 4).

The device 20 is then carefully drawn distally until the flange 11 abuts against the inside surface of the artery 17 (see Fig. 5). The detents 24 are then depressed to allow the plug introducer sheath 22 to slide distally over the pusher tube 23, which is held stationary. This releases the remainder of the plug 10 from the compressive restraint of the plug introducer sheath 22 and the plug 10 is thus deployed in the puncture 26 (see Fig. 6). In this position the intermediate portion 14 expands to occlude the puncture 26, the flange 11 bears against the inside surface of the arterial wall and the cylindrical body 15 lies on the outer side of the arterial wall. The ribs 16 on the cylindrical body 15 serve to help retain the cylindrical body in place in the tissue surrounding the artery 17.

The plug introducer sheath 22 and the guidewire 19 are then withdrawn and the procedure is completed (see Fig. 7).

As depicted in Fig. 8, the plug 10 may be provided with reinforcing wires 31 to stiffen it and prevent it from being pulled through the puncture 26 in the artery wall 17. The wires 31 may be formed of Nitinol or another material that will change shape at the temperature of blood, or alternatively, a spring material. In this way, the wires could be designed to unfold like the ribs of an umbrella upon the proximal end 32 of the plug 10 being projected from the end of the plug introducer sheath 22 into the blood stream in the artery 17. The wires could also unfold upon both the proximal 32 and distal 33 ends of the plug 10 thus further reinforcing the plug 10 and preventing its dislodgment from the puncture 26. The wires 31 may be further adapted such that they project towards the wall of the artery 17 surrounding the puncture 26 thereby anchoring the plug 10 on both the intraluminal and endoluminal walls of the artery (as shown in Fig 9).

In another embodiment of the invention, the plug 10 may be adapted such that it does not extend into the artery 17 but instead is placed within the tissue directly adjacent the puncture 26 such that upon expansion of the plug 10, the puncture 26 is occluded (as shown in Fig. 10).

As is depicted in Fig. 11, the plug 10 of the present invention can be further anchored within the tissue surrounding the artery 17 by way of engagement members 34 which are disposed around the wall of the distal end 33 of the plug 10, and which extend into the tissue around the artery 17; thereby preventing the plug 10 from dislodging and entering the artery 17 through the puncture 26. The engagement members 34 can be made from Nitinol, or another material which changes shape at body temperature, or alternatively, a spring material, such that upon deployment of the plug 10 in the puncture 26, the engagement members 34 take on an expanded configuration such that they extend outwardly from, and at an angle to, the wall of the distal end 33 of the plug 10.

In another embodiment, the proximal end 32 of the plug 10 is made from a thin layer of vascular graft material 30 such as PTFE, polyester with reinforcing wires 31 internal the thin layer of vascular graft material 30. The wire is preferably made from a shape memory or self expanding material.

In a further embodiment as depicted in Fig 12, the plug 10 is adapted to take on an angled configuration in its compressed state such that it follows the angle of the plug introducer sheath 22, ensuring that the plug 10 will be in the correct position, ie. in line with the puncture 26, upon deployment of the plug 10 from the plug introducer sheath 22.

In another embodiment of the invention depicted in Figs. 13a and 13b, the plug 10 is funnel-like in shape with its distal end 33 greater in cross sectional area than its proximal end 32. Following placement of the plug 10 into the puncture 26, the free end 35 of the guidewire 19 is left in place within the artery 17. The guidewire 19 is adapted to have a capture member 36 adjacent its free end 35, whereupon withdrawal of the guidewire 19 causes the capture member 36 to pull the proximal end 32 of the plug 10 up within the plug 10 thereby minimising the length of plug 10 left within the artery 17. With the capture member 36 lodged internal the plug 10, the guidewire 19 may be tied off, cut and withdrawn from the patient's body.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. A device for the occlusion of a puncture in the wall of a bodily duct, the device comprising a resiliently compressible plug that can be introduced into the puncture from externally of the body, and introduction means adapted to introduce the plug into the puncture in a radially compressed state and to then release the plug within the puncture so that it may expand to occlude the puncture.

2. The device of claim 1, wherein the plug is formed with a region of reduced cross sectional area intermediate its ends.

3. The device of claim 2, wherein the region of reduced cross-sectional area is bounded on at least one side, at the proximal end of the plug, by at least one enlargement such that once the plug has been deployed in the puncture and allowed to expand it will resist withdrawal in a direction away from the, or each, enlargement.

4. The device of claim 3, wherein the enlargement at the proximal end of the plug is convex on its side facing into the bodily duct with a relatively long radius of curvature.

5. The device of claim 3 or 4, wherein a distal end of the plug, which projects outwardly from the wall of the bodily duct, is formed with ridges, or other projections, that inhibit movement of the plug towards the lumen of the vessel.

6. The device of any one of claims 3 to 5, wherein the face of the enlargement facing into the lumen of the bodily duct is provided with an anti-coagulant coating.

7. The device of any one of the preceding claims, wherein the plug is formed from a resorbable polymer or polycarbonate foam or sponge material.

8. The device of claim 7, wherein the plug is formed of a polymer sponge that has an expansion ratio of from about 1.5:1 up to about 10:1.

9. The device of any one of the preceding claims, wherein the material of the plug is naturally resilient such that it will spring back into shape as soon as a compressive pressure has been removed.

10. The device of any one of claims 1 to 8, wherein the material of the plug is formed of a material that is compressed or contracted through dehydration.

11. The device of any one of the preceding claims, wherein the plug contains within its structure, metallic wires or wireforms.

12. The device of claim 1, wherein the plug comprises a main body having a proximal end and a distal end of greater cross sectional area than the proximal end, wherein upon expansion of the plug, the proximal end is positioned within the lumen of the vessel and the distal end within the tissue surrounding the vessel.

13. The device of claim 1, wherein the plug is funnel-like in shape.

14. A method for occluding a puncture in the wall of a bodily duct, the method including the steps of:-

(a) introducing a resiliently compressible plug from externally of the body into the puncture in a compressed state; and

(b) releasing the compression from the plug so that it may expand in the puncture and occlude it.

15. The method of claim 14, wherein the plug is deliverable to the puncture site through an introduction sheath that has already been inserted into the patient for the operation.

16. The method of claim 15, wherein the plug is loaded into a plug delivery sheath that will slide into the existing delivery sheath but which is slightly longer than that sheath.

17. The method of claim 16, wherein once the plug delivery sheath is in place, further comprising the steps of:

(i) withdrawing the original sheath;

(ii) pushing the plug down the plug delivery sheath until an enlargement at a proximal end of the plug projects from the end of the sheath; and

(iii) withdrawing the plug delivery sheath gently from the wound until the enlargement engages against the inside of the vessel wall and is pulled free of the proximal end of the plug delivery sheath.

18. The method of claim 17, wherein a pusher is provided inside the plug delivery sheath to assist in the ejection of the plug from the end of the plug delivery sheath.

19. The method of claim 18, wherein stop means are provided on the plug delivery sheath or on the pusher such that initially they may be moved relative to one another by an amount just sufficient to project the enlargement of the plug beyond the end of the sheath so preventing the plug from being fully deployed within the duct.

20. The method of any one of claims 16 to 19, wherein the plug delivery sheath is introduced into the patient at an angle and the plug has, in its compressed state, a configuration that follows the angled plug delivery sheath.

21. The method of claim 14, wherein the plug is funnel-like in shape and is positioned within the puncture by means of a guidewire and a plug delivery sheath such that the free end of the guidewire extends into the lumen of the vessel, the guidewire, having disposed on its free end, a capture member which, upon withdrawal of the guidewire abuts against a proximal end of the plug, such that the proximal end of the plug is pulled internal the funnel-like structure of the plug, thereby minimising the length of plug within the duct, and therefore, minimising obstruction of any blood flow in the duct.

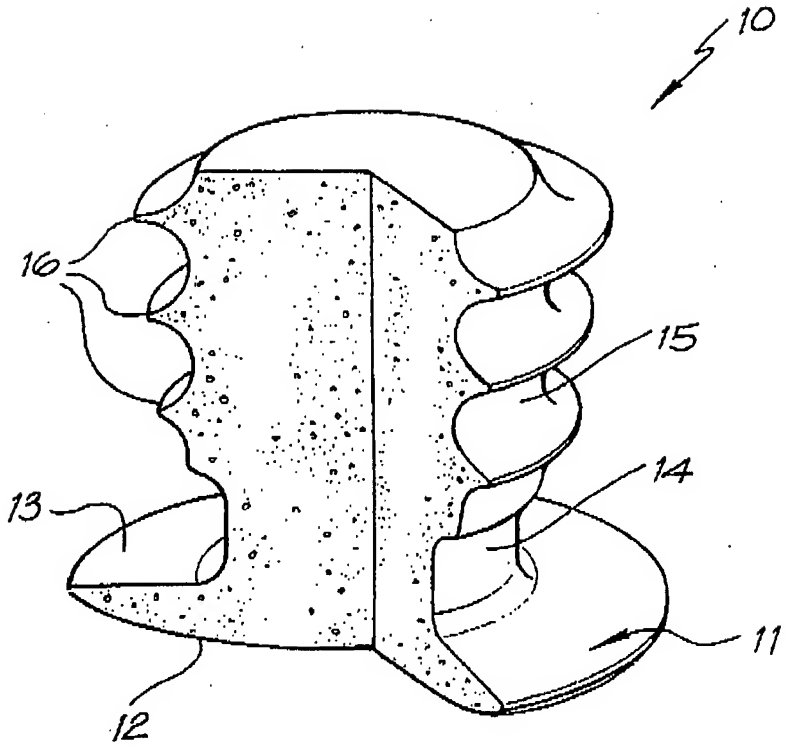


FIG. 1

FIG. 2

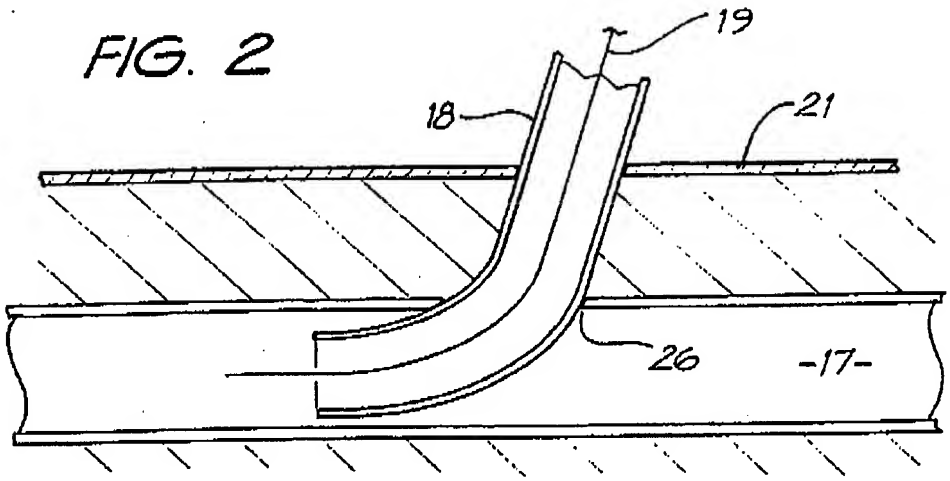
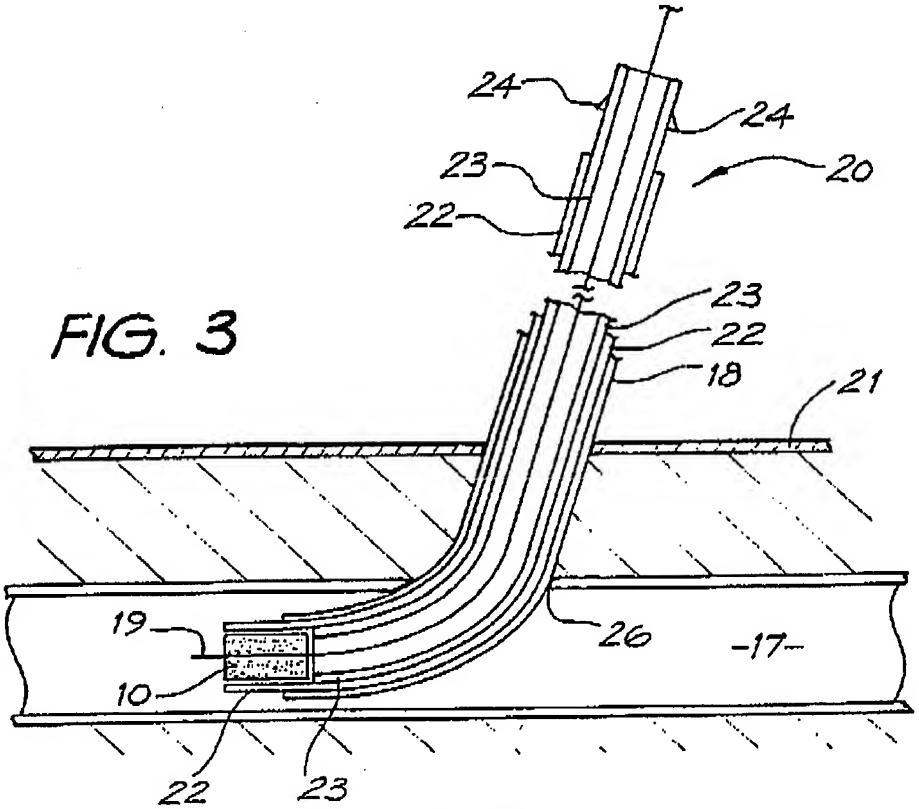


FIG. 3



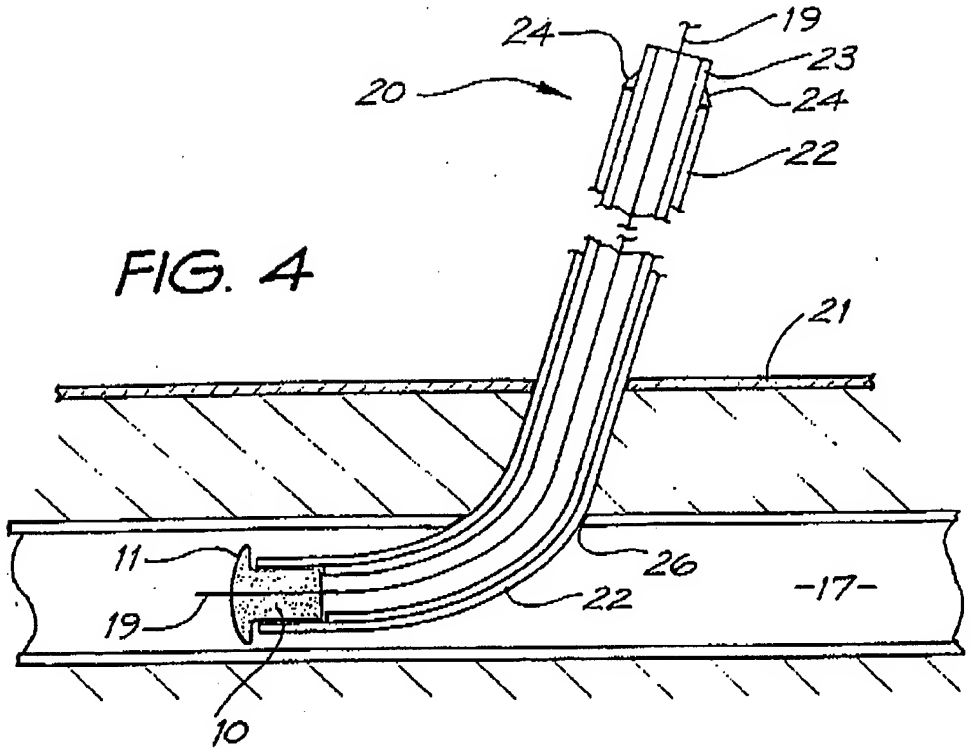


FIG. 4

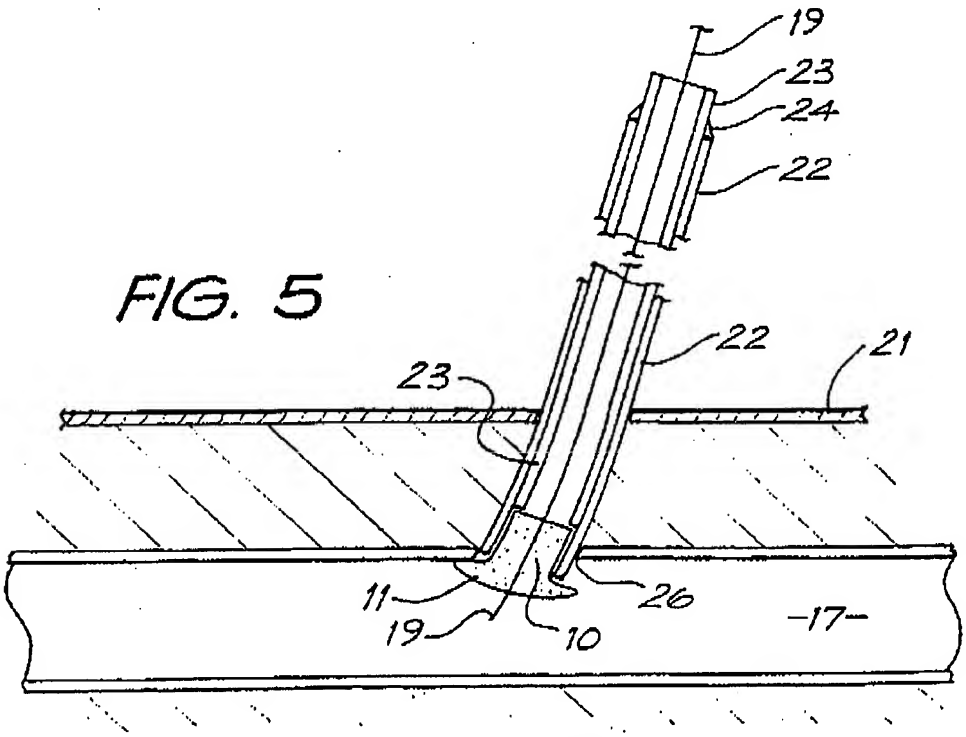


FIG. 5

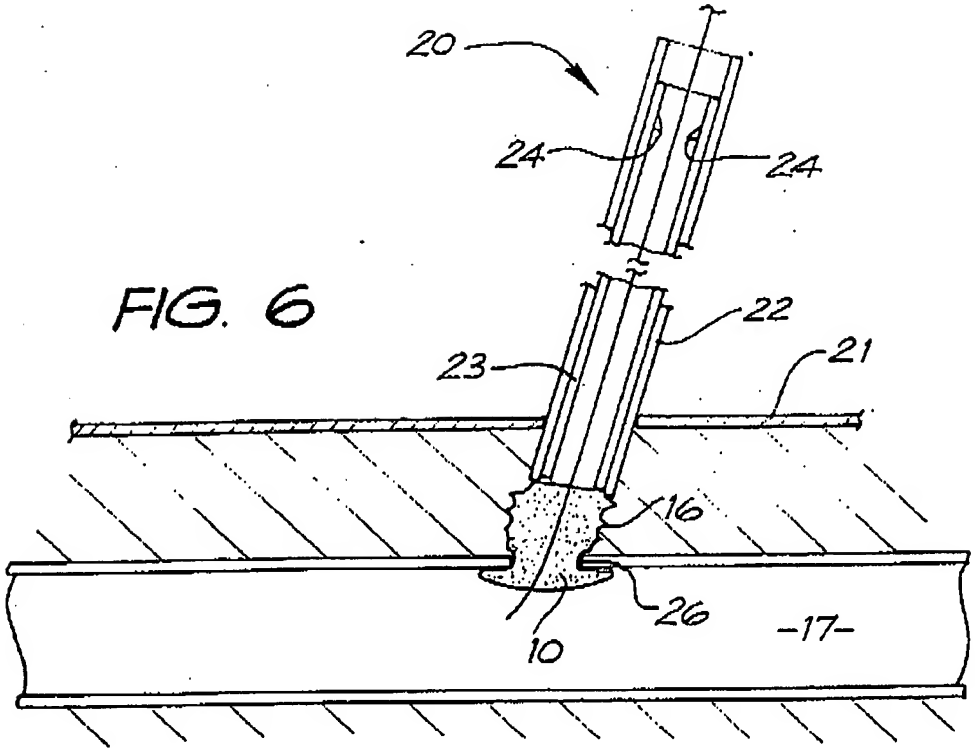


FIG. 6

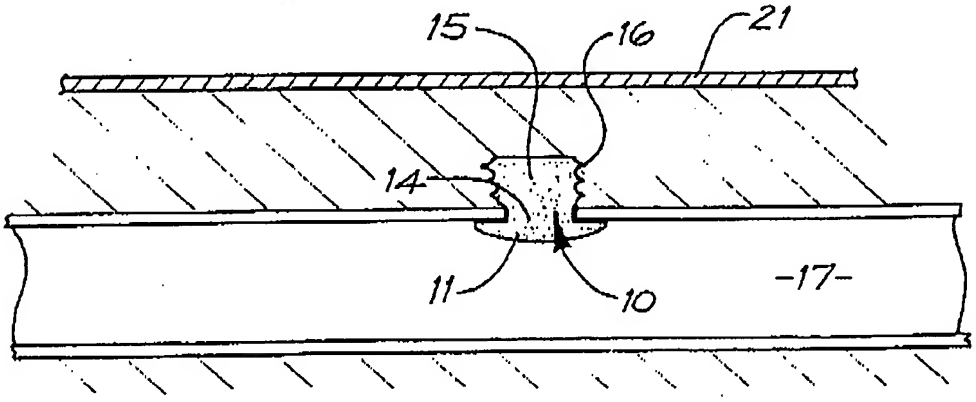


FIG. 7

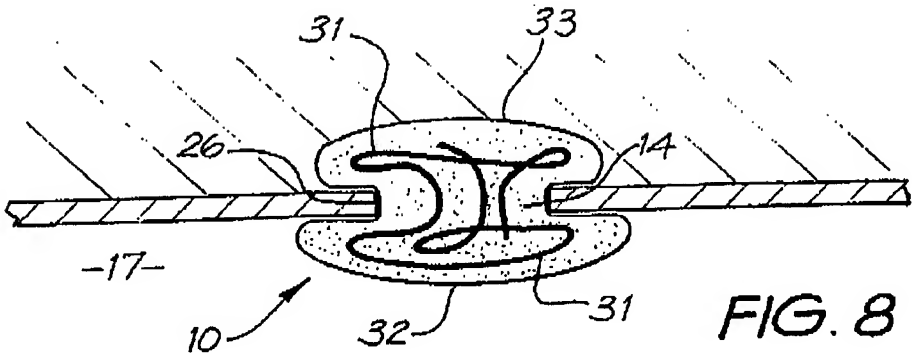


FIG. 8

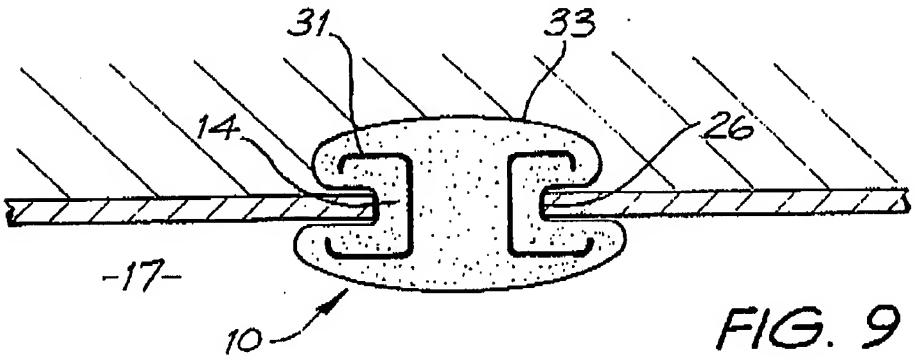


FIG. 9

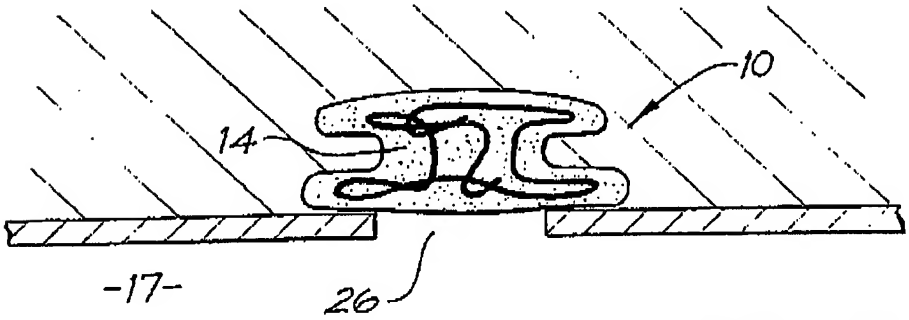


FIG. 10

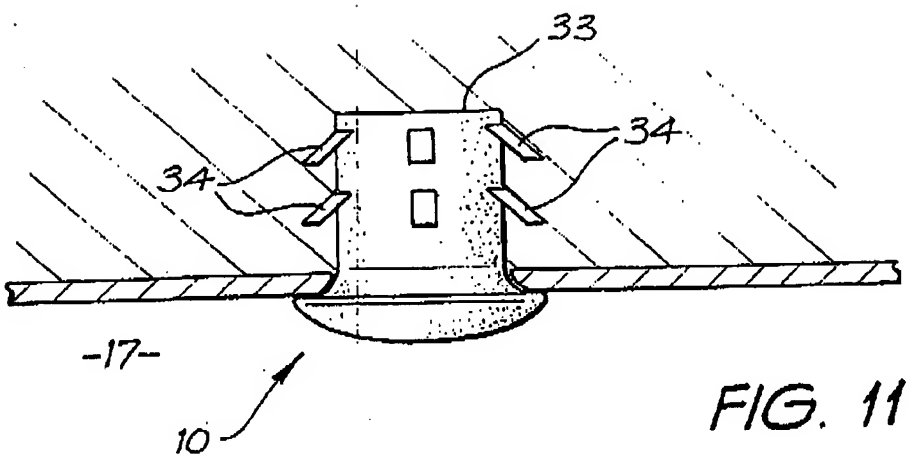


FIG. 11

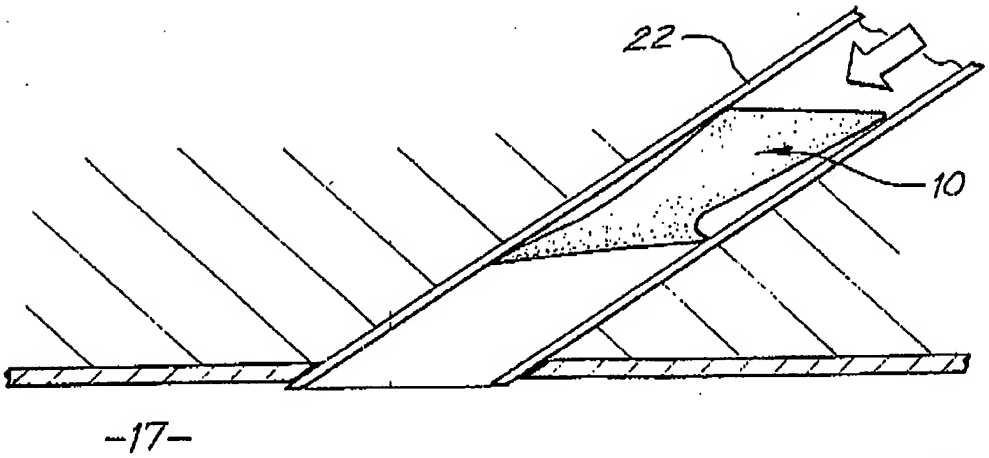


FIG. 12

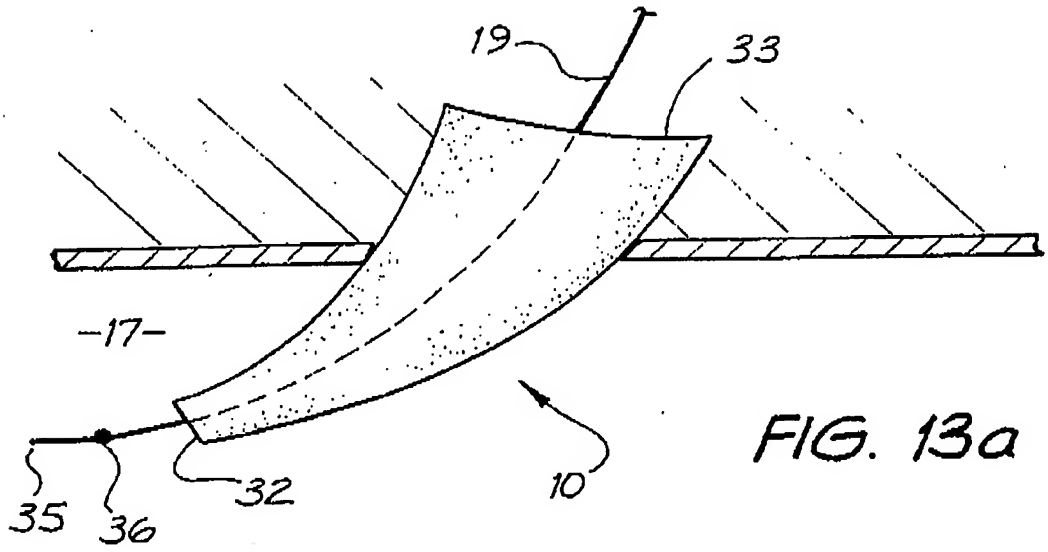


FIG. 13a

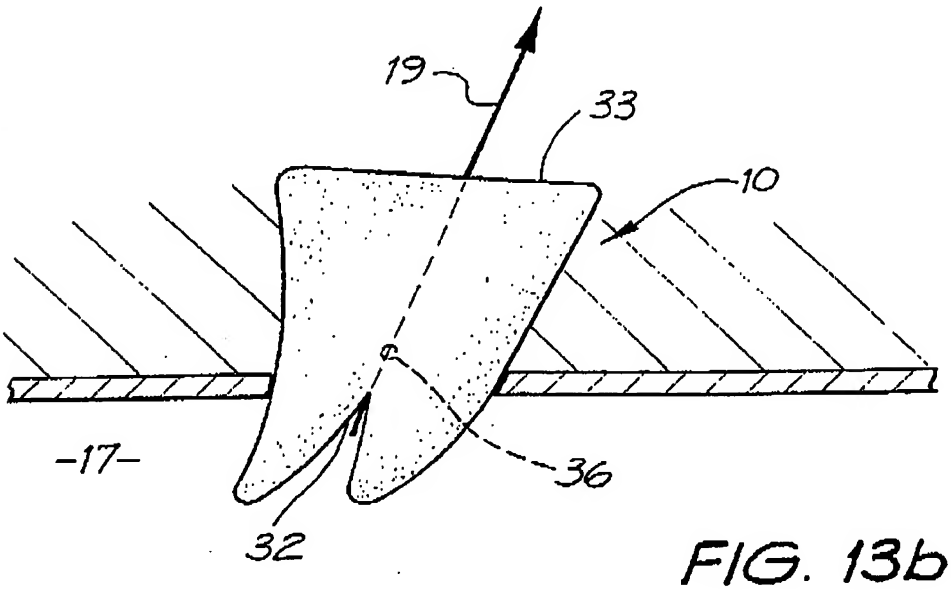


FIG. 13b

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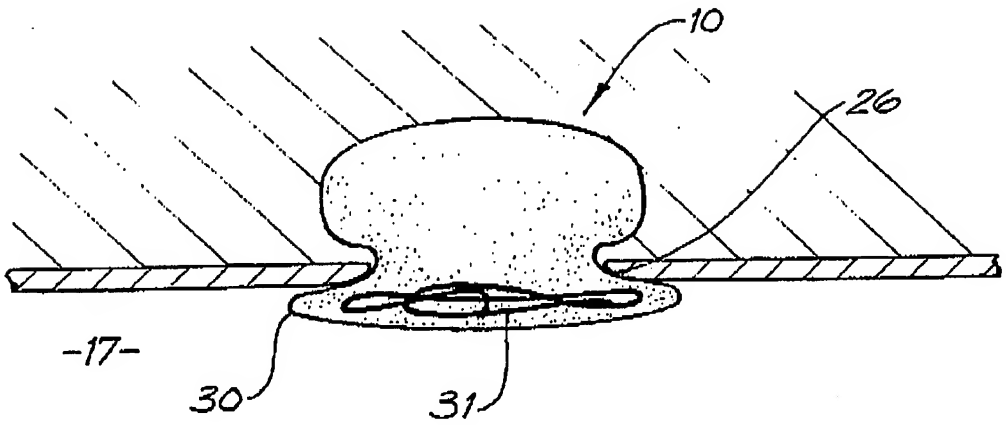

FIG. 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00847

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61B 17/03

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B 17/-, 19/-, A61M 25/-, 39/-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT & JAPIO + keywords

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5192301 A (Kamiya et al.) 9 March 1993 see abstract, figures, col 2 lines 57-63	1-6, 9, 11-20
X	WO 98/19605 A (Li) 14 May 1998 see abstract, figures	1, 7-10, 14-20
X	WO 95/26683 A (Boston Scientific Corp) 12 October 1995 see whole document	1,7,8,10,14-20

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 November 1999	25 NOV 1999

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 99/00847

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5061274 A (Kensey) 29 October 1991 see whole document	1, 10, 11-21
X	WO 89/11301 A (Kensey Nash Corp) 30 November 1989 see whole document	1-12, 14-21

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 99/00847

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
US	5192301	FR	2641692	JP	2277459		
WO	98/19605	CN	1218378				
WO	95/26683	US	5643318				
US	5061274	EP	609212	US	5192302	AU	30566/92
		EP	619718	WO	9308743	WO	9307813
WO	89/11301	US	4890612	CA	1322922	EP	422046
		HK	1007272	JP	63246148	US	4744364
		US	4852568				

END OF ANNEX